REMARKS

By this Amendment, claims 2, 4-7, 9 and 10 have been amended, claim 1 has been cancelled, and new claims 13-23 have been added. Thus, claims 2-23 are pending in this application. Reexamination and reconsideration of the application are respectfully requested.

In item 2 on page 2 of the Office Action, the specification is objected to for failing to indicate that this application is a 371 National Stage entry of PCT/JP 03/13991, filed on 10/31/2003. Applicants submit that the amendments made to the specification overcome the objection. Withdrawal of the objection is respectfully requested.

In items 3 and 4 on page 2 of the Office Action, claims 6-12 are rejected under 35 U.S.C. §112, second paragraph. Applicants submit that the amendments made to the specification overcome the rejection. Withdrawal of the rejection is respectfully requested.

In items 6 and 7 on page 3 of the Office Action, claims 1-5 are rejected under 35 U.S.C. §102(b) as being anticipated by Nankai et al. (U.S. Patent No. 5,120,420). This rejection is believed moot in view of the cancellation of claim 1. Furthermore, the rejection is believed clearly inapplicable to amended independent claim 2, for the following reasons.

Independent claim 2 recites, among other features, a standard solution that includes a reducing substance and a predetermined amount of substrate, the standard solution controlling the precision of measurement of the measurement apparatus by checking whether a measured substrate concentration is within a predetermined range or not. Claim 2 also recites that when a first potential is applied to an electrode portion of a biosensor to which the standard solution is supplied, by a driving power supply of a measurement apparatus, the standard solution shows an oxidation current waveform which is definitely different from and is larger than a waveform which is obtained when the first potential is applied to the electrode portion of the biosensor to which the sample solution is supplied; and when a second potential smaller than the first potential is applied to the electrode portion of the biosensor to which the standard solution is supplied, the standard solution shows an oxidation current waveform which is approximately the same as a waveform which is obtained when the second potential is applied to the electrode portion of the biosensor to which the sample solution is supplied. Nankai et al. cannot reasonably be considered to disclose the claimed standard solution.

The Office Action asserts that Nankai et al., at col. 9, lines 31-54, discloses a standard solution that can reasonably be considered to correspond to the claimed standard solution. Applicants respectfully disagree with this assertion. The glucose standard solution in Nankai et al. is a mere sample that is tested to determine its contents. Specifically, the glucose standard solution discussed in col. 9, lines 31-54, is used to measure precisely or to simplify measurements, when a blood sample is tested under normal circumstances. In this regard, the glucose standard solution in Nankai et al. may be used as a substitute for blood, not as a solution to control a precision of a measurement apparatus.

To the contrary, the standard solution as recited in claim 2 is used to control a precision of a measurement apparatus, and is characterized in that the obtained current waveform is distinguished from that of blood. In this regard, the standard solution as recited in claim 2 is distinguished from the glucose standard solution disclosed in Nankai et al., and has a use that is different from that in Nankai et al. Moreover, the standard solution cannot be replaced by blood. For at least these reasons, the standard solution in Nankai et al. cannot reasonably be considered to correspond to the claimed standard solution.

Furthermore, Nankai et al. does not disclose that when a first potential is applied to an electrode portion of a biosensor to which a glucose standard solution is supplied, by a driving power supply of a measurement apparatus, the glucose standard solution shows an oxidation current waveform which is definitely different from and is larger than a waveform which is obtained when a first potential is applied to an electrode portion of the biosensor to which the sample solution is supplied, as required by claim 2. Also, Nankai et al. does not disclose that when a second potential smaller than the first potential is applied to the electrode portion of the biosensor to which a glucose standard solution is supplied, the glucose standard solution shows an oxidation current waveform which is approximately the same as a waveform which is obtained when the second potential is applied to the electrode portion of the biosensor to which the sample solution is supplied, as required by claim 2.

For at least its failure to disclose the claimed standard solution, Nankai et al. cannot reasonably be considered to disclose all of the features positively recited in independent claim 2.

Furthermore, claims 3-5 are also not disclosed by Nankai et al., by virtue of their dependencies. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

In item 12 on page 4 of the Office Action, claims 1-4 are rejected under 35 U.S.C. §102(b) as being anticipated by Ye (U.S. Patent No. 5,723,284). This rejection is believed moot in view of the cancellation of claim 1. Furthermore, the rejection is believed clearly inapplicable to amended independent claim 2, for the following reasons.

As noted above, independent claim 2 recites, among other features, a standard solution that includes a reducing substance and a predetermined amount of substrate, the standard solution controlling the precision of measurement of the measurement apparatus by checking whether a measured substrate concentration is within a predetermined range or not. Applicants submit that Ye does not discloses a standard solution that includes a reducing substance.

Generally, in a glucose sensor having an electrode, the electron passes through a path that includes glucose—>enzyme--) mediator--) electrode. As a result of this process, it is possible to determine the oxidation current based on the glucose concentration. The enzyme and the mediator are provided in dry condition in the sensor in advance. Ye discloses such a glucose sensor. For example, the reduced mediator (ferricyanide) in Ye is provided in dry condition in the sensor in advance. Importantly, the ferricyanide is provided in the sensor, and is not included in the glucose standard solution that is applied to the glucose sensor.

In the exemplary embodiments of the present invention, by making the standard solution include a reducing substance, it is easy to detect the differences between the standard solutions during the first potential time period. For example, the reducing substance generates a large waveform that is larger than the voltage waveform which is generated by the standard solution during the first potential time period.

Thereby, in the exemplary embodiments of the present invention, the adequate voltage waveform is formed even in a case that the concentration of substrate is low during the first potential time period. Accordingly, it is possible to detect that the standard solution is supplied, and to see the clear difference from the sample solution.

To the contrary, in the Ye reference, during the first potential time period, since the waveform of the standard solution is smaller than that of the sample solution, the adequate

voltage waveform is not formed. Consequently, the measurement apparatus cannot detect that the standard solution is supplied, and it is difficult to see the difference from the sample solution in a case where the concentration of substrate is low. As noted above, in the exemplary embodiments of the present invention, this is not the case. According to the exemplary embodiments of the present invention, by making the standard solution include a reducing substance, it is possible to carry out a high precision discrimination between solutions.

For at least the above reasons, Ye fails to disclose a standard solution that includes a reducing substance and a predetermined amount of substrate, the standard solution controlling the precision of measurement of the measurement apparatus by checking whether a measured substrate concentration is within a predetermined range or not, as required by claim 2. Furthermore, claims 3 and 4 are also not disclosed by Ye, by virtue of their dependencies. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

In items 15 and 16 on page 5 of the Office Action, claims 6, 7, 9 and 11 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ye in view of WO 02//44705 (hereinafter "WO '705"). Claim 6 has been amended to depend from independent claim 2, and claims 7, 9 and 11 depend from claim 6. Thus, claims 6, 7, 9 and 11 are therefore allowable at least by virtue of their dependencies.

Furthermore, claim 6 is allowable over the combination of applied references for the additional features recited therein. For example, claim 6 recites a method for determining a substrate contained in a sample solution on the basis of an oxidation current value which is obtained by applying a first potential from a driving power supply of a measurement apparatus to an electrode portion of a biosensor including the electrode portion having a counter electrode and a measuring electrode, as well as a reagent layer reacting with the sample solution supplied to the electrode portion for a first time period, and then stopping the application of the potential for a given time period, and applying a second potential smaller than the first potential to the electrode portion for a second time period after the given time period has passed, and a standard solution containing a reducing substance is supplied to the electrode portion of the biosensor as a standard solution used for controlling a precision of measurement of the measurement apparatus, and it is judged whether a kind of analyte liquid supplied to the biosensor is the sample solution

or the standard solution on the basis of the oxidation current value that is obtained by applying the first potential and the oxidation current value that is obtained by applying the second potential.

Ye fails to disclose or suggest these features. To the contrary, in Ye, by adding organic solvent to a control solution, the concentration of the mediator in the test solution will be reduced at an early stage of the test, i.e., the burn period, thereby the burn current is reduced relative to the lead current resulting in a dynamic profile which is different from that generated by a pure aqueous test sample such as blood.

Furthermore, the EP 1156234 reference also fails to disclose or suggest these features. In EP 1156234, the predetermined voltage is applied before the sample is supplied. Then the application of the voltage is stopped for a certain period after the sample is supplied. Thereafter the same voltage is applied again and the measurement of the current value is conducted after the reapplication of the voltage. The sample is thus determined according to this process.

Importantly, in Ye and EP 1156324, the measurement apparatus does not identify a kind of analyte liquid automatically on the basis of the oxidation current value that is obtained by applying the first potential for a first time period and the oxidation current value obtained by applying the second potential for a second time period as required by claim 6.

Additionally, new claims depend directly or indirectly from independent claim 1. Therefore, new claims 13-23 are therefore allowable at least by virtue of their dependencies.

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is clearly in condition for allowance. An early notice thereof is earnestly solicited.

If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, it is respectfully requested that the Examiner contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

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